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# Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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	Application No.	Applicant(s)				
Office Action Occurrence	10/566,094	MERCE VIDAL ET AL.				
Office Action Summary	Examiner	Art Unit				
	CRAIG RICCI	1614				
The MAILING DATE of this communication app Period for Reply	ears on the cover sheet with the c	orrespondence address				
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period w  - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 6(a). In no event, however, may a reply be timil apply and will expire SIX (6) MONTHS from cause the application to become ABANDONEI	lely filed the mailing date of this communication. (35 U.S.C. § 133).				
Status						
1) Responsive to communication(s) filed on 28 No.	ovember 2008					
,— · · · · · · · · · · · · · · · · · · ·	action is non-final.					
3) Since this application is in condition for allowan		secution as to the merits is				
closed in accordance with the practice under E						
Disposition of Claims						
4)⊠ Claim(s) <u>1-14,18,19,46,47 and 74-93</u> is/are per	nding in the application.					
	4a) Of the above claim(s) is/are withdrawn from consideration.					
5) Claim(s) is/are allowed.						
6) Claim(s) <u>1-14,18,19,46,47,74-82, 84-90 and 92</u>	2-93 is/are rejected.					
7)⊠ Claim(s) <u>83 and 91</u> is/are objected to.						
8) Claim(s) are subject to restriction and/or	election requirement.					
Application Papers						
9)☐ The specification is objected to by the Examine						
10) ☐ The drawing(s) filed on is/are: a) ☐ acce		Examiner.				
Applicant may not request that any objection to the o						
Replacement drawing sheet(s) including the correcti						
11) The oath or declaration is objected to by the Ex		, ,				
Priority under 35 U.S.C. § 119						
12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of:	priority under 35 U.S.C. § 119(a)	-(d) or (f).				
1. Certified copies of the priority documents	s have been received					
2. Certified copies of the priority documents		on No				
3. Copies of the certified copies of the prior						
application from the International Bureau	*	a in the National Stage				
* See the attached detailed Office action for a list of		d				
Goo the attached actained emice action for a list of	or the continion depice het receive	<b>u</b> .				
Attachment(s)	□	(DTO 440)				
Notice of References Cited (PTO-892)     Notice of Draftsperson's Patent Drawing Review (PTO-948)	4) ∐ Interview Summary Paper No(s)/Mail Da					
3) X Information Disclosure Statement(s) (PTO/SB/08)	5) Notice of Informal P					
Paper No(s)/Mail Date <u>11/28/2008</u> .	6)					

# **DETAILED ACTION**

### Status of the Claims

- 1. The amendments filed 11/28/2008 were entered.
- 2. The rejection of claim 14 under 35 U.S.C. 112, second paragraph, has been withdrawn in view of Applicant's amendment.
- 3. The rejection of claims 1-7, 9-13, 18-19 and 46-47 under 35 U.S.C. 112, second paragraph, has been withdrawn in view of Applicant's amendment.
- 4. The rejection of claims 9 and 14 under 35 U.S.C. 102(b) over *Merce-Vidal et al* has been withdrawn in view of Applicant's amendment.

### Response to Arguments

5. Applicants' arguments, filed 11/28/2008, have been fully considered.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

#### Election/Restrictions

6. As previously discussed, Applicant's elected Group I with traverse in the reply filed on 5/21/2008. Lack of unity was based on the fact that instant claim 14 originally included the compound N-[3-(2-diethylaminoethyl)-1H-indole-5-yl]-5-chloro-3-methylbenzo[b]thiophene-2-sulfonamide (claim 14, example 24) and furthermore *Merce-Vidal et al* (WO 03/042175 A1) teach N-[3-(2-diethylaminoethyl)-1H-indole-5-yl]-5-chloro-3-methylbenzo[b]thiophene-2-sulfonamide (Page 5, Lines 7-8, Example 1).

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However, the compound was misnamed and example 24 should have read N-[1-(2-diethylaminoethyl)-1H-indole-5-yl]-5-chloro-3-methylbenzo[b]thiophene-2-sulfonamide. This has been corrected by amendment. Nevertheless, as previously stated, unity of

invention is broken based on Merce-Vidal et al as discussed in the previous Action.

Namely, for the reasons reiterated below in the instant Action.

7. The requirement is still deemed proper and is therefore made FINAL.

# Claim Rejections - 35 USC § 103

- 8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
- 10. Claims 1-14, 18-19, 46-47, and 74-82, 84-90 and 92-93 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Merce-Vidal et al* (cited in a previous Action) in view of *Filla et al* (cited in a previous Action).

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11. The following rejection is necessitated by amendment.

12. As discussed in the previous Action mailed on 07/29/2008, the instant invention is drawn to compounds which are useful as 5-HT<sub>6</sub> modulators. Specifically, instant claim 1 is drawn to compounds of formula (Ia) which encompasses the following specific

compound wherein R1 is NR<sup>8</sup>R<sup>9</sup> and

R<sup>8</sup>R<sup>9</sup> together with the bridging nitrogen atom form a saturated heterocyclic ring,

specifically; R2-R7 are hydrogen; and A is a polycyclic aromatic ring system, wherein the rings are 6 membered. Specifically, the above compound is disclosed in the instant Specification as N-[1-(2-pyrrolidine-1-yl-ethyl)-1H-indole-5-yl]-naphthalene-1-sulfonamide (Page 78, Example 17) and the compound reads on claims 1-8 and newly added claims 76-82.

13. *Merce-Vidal et al* teach compounds which are useful as 5-HT<sub>6</sub> modulators. In particular, *Merce-Vidal et al* disclose the compound N-{3-[2-(pyrrolidin-1-yl)-ethyl]-1H-

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indole-5-yl}-naphthalene-1-sulfonamide, having the following structure:

(Page 6, Example 45).

- 14. Accordingly, the only difference between the instant specie and that taught by *Merce-Vidal et al* is the placement of -(CH<sub>2</sub>) <sub>n</sub>-R<sub>1</sub> (wherein -(CH<sub>2</sub>) <sub>n</sub>-R<sub>1</sub> in the instant invention and in *Merce-Vidal et al* are the same) on the indole core. The subtle differences that stem between the shift of -(CH<sub>2</sub>) <sub>n</sub>-R<sub>1</sub> from position 3 on the indole ring (as in *Merce-Vidal et al*) to position 1 on the indole ring (as in the instant application) are irrelevant since the MPEP 2144.09 states "Compounds which are position isomers (compounds having the same radicals in physically different positions on the same nucleus) or homologs (compounds differing regularly by the successive addition of the same chemical group, e.g., by -CH2- groups) are generally of sufficiently close structural similarity that there is a presumed expectation that such compounds possess similar properties. *In re Wilder*, 563 F.2d 457, 195 USPQ 426 (CCPA 1977).
- 15. Furthermore, as discussed in the previous Action, the person of ordinary skill in the art at the time the invention was made would have found it obvious to substitute the indole ring at position 1 in view of *Filla et al* which teach 5-HT<sub>6</sub> modulators which are substituted at position 1 of their indole ring. Specifically, *Filla et al* teach the following

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compounds:

(Page 67, Example 28) and

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(Page 68, Example 29). Thus, at the time the

invention was made, one of ordinary skill in the art would have been motivated to take the -( $CH_2$ )  $_n$ - $R_1$  group or similar variants, and place it at various positions on the indole ring (for example at position 1) to give 5-HT $_6$  modulators. Thus, the claims are obvious under 35 U.S.C. 103(a).

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16. Instant claim 9 is drawn to compounds of formula (lb) which encompasses the

following specific compound

wherein R1 is

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NR<sup>8</sup>R<sup>9</sup> and R<sup>8</sup> and R<sup>9</sup> are each CH<sub>3</sub>; R2-R7 are hydrogen; and A is a polycyclic aromatic ring system, wherein the rings are 6 membered. Specifically, the above compound is disclosed in the instant Specification as N-[1-(2-dimethylaminoethyl)-1H-indole-5-yl]-naphthalene-1-sulfonamide (claim 14, Example 3) and the compound reads on claims 9-14 and newly added claims 86-90.

17. *Merce-Vidal et al* disclose N-[3-(2-dimethylaminoethyl)-1H-indole-5-yl]-naphthalene-1-sulfonamide (Page 5, Line 3, Example 8) having the following structure:

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- 18. Accordingly, the only difference between the instant specie and that taught by *Merce-Vidal et al* is the placement of instant -(CH<sub>2</sub>) <sub>n</sub>-R<sub>1</sub> (wherein -(CH<sub>2</sub>) <sub>n</sub>-R<sub>1</sub> are the same) on the indole core. The subtle differences that stem between the shift of -(CH<sub>2</sub>) <sub>n</sub>-R<sub>1</sub> from position 3 on the indole ring (as in *Merce-Vidal et al*) to position 1 on the indole ring (as in the instant application) are obvious since the MPEP 2144.09 states "Compounds which are position isomers (compounds having the same radicals in physically different positions on the same nucleus) or homologs (compounds differing regularly by the successive addition of the same chemical group, e.g., by -CH2- groups) are generally of sufficiently close structural similarity that there is a presumed expectation that such compounds possess similar properties. *In re Wilder*, 563 F.2d 457, 195 USPQ 426 (CCPA 1977).
- 19. Furthermore, as discussed above, *Filla et al* teach 5-HT<sub>6</sub> modulators containing the same instant core substituted at position 1 of the indole ring. Accordingly, one of ordinary skill in the art would have been motivated to take the -(CH<sub>2</sub>)  $_n$ -R<sub>1</sub> group or similar variants, and place it at various positions on the indole ring (for example at position 1) to give 5-HT<sub>6</sub> modulators. Thus, the claims are obvious under 35 U.S.C. 103(a).
- 20. <u>FIRST</u>, Applicant traverses on the grounds that the present invention lacks the "tryptamine"-like structure of the compounds disclosed in *Merce-Vidal et al*:

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(Applicant Argument, Page 28). As discussed above,

Merce-Vidal et al teach compounds which are 5-HT6 modulators which are identical to the instant compounds except that the indole core of the compound taught by Merce-Vidal et al is substituted at position 3, as opposed to position 1. However, Applicant's characterization of the compounds taught by Merce-Vidal et al as having a tryptaminelike structure do not overcome above discussed reasons as to why the instant compounds are obvious in view of Merce-Vidal et al. The compounds are position isomers differing in the placement of -(CH<sub>2</sub>) <sub>n</sub>-R<sub>1</sub> (wherein -(CH<sub>2</sub>) <sub>n</sub>-R<sub>1</sub> in the instant invention and in Merce-Vidal et al are the same) on the indole core. In view of In re Wilder and Filla et al, the skilled artisan would have been motivated to make the instant compounds in the expectation that that such compounds would possess similar properties. Although Applicant is correct that Merce-Vidal et al do not explicitly teach moving the amino moiety or the N-containing ring to the 1-position (Applicant Argument, Page 28), an explicit teaching is not required. As stated by the Court in KSR Insternational Co. v. Teleflex Inc., 82 USPQ2d 1385 (U.S. 2007), "the analysis need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of Application/Control Number: 10/566,094

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ordinary skill in the art would employ." In the instant case, a person of ordinary skill in the art would have found it obvious to move the amino moiety or the N-containing ring to the 1-position as discussed; namely, in view of *In re Wilder* and *Filla et al* with the reasonable expectation that the *prima facie* obvious compounds would possess similar properties. Accordingly, Applicant's argument is not found persuasive.

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- 21. **SECOND**, Applicant traverses on the grounds that moving substituents from position 3 to position 1 on the indole cores of other compounds dramatically changes the properties of those compounds. However, while the instant Application is drawn to compounds which are useful as modulators of 5-HT<sub>6</sub> (and whereas Merce-Vidal et al and Filla et al are drawn to compounds which modulate 5-HT<sub>6</sub>), none of the compounds referenced by Applicant are drawn to modulators of 5-HT<sub>6</sub>. Thus, the compounds referenced by Applicant do not bear on the reasonable expectation of functionality established by the prior art teachings of *Merce-Vidal et al* and *Filla et al*. Accordingly, Applicant's argument is not found persuasive.
- 22. **THIRD**, Applicant traverses on the grounds that *Filla et al* do not teach compounds wherein position 1 of the indole ring is substituted by a - $(CH_2)_n$ - $R_1$  group  $(R_1 \text{ being NR}^8R^9 \text{ or a nitrogen containing ring})$ . Applicant is directed to Example 25 of

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Filla et al (Page 64, Example 25). Applicant

notes that *Filla et al* did not contain any experimental data about the biological activity of the compounds described do not disclose any information at all regarding possible biological activities of positional isomers. Accordingly, Applicant concludes that the skilled artisan would not expect the compounds to have similar activity. Applicant's argument is not persuasive. As discussed, both *Merce-Vidal et al* (Page 2, Lines 25-26) and *Filla et al* (Title) disclose compounds which are alleged modulators of 5-HT<sub>6</sub>. In particular, *Merce-Vidal et al* teach compounds which differ from the instant compound in the substitution of the indole ring (position 3 vs. position 1). Thus, as previously discussed, the skilled artisan would expect position isomers of the compounds taught by *Merce-Vidal et al* to possess similar properties in view of *In re Wilder*. Furthermore, in view of *Filla et al* who teach modulators of of 5-HT<sub>6</sub> having a similar substitution at position 1 of the indole core, the skilled artisan would have reasonably predicted that position 1, specifically, could support the substituent taught by *Merce-Vidal et al*.

23. **FOURTH**, Applicant cites *Takeda Chemical Industries Ltd. V. Alphapharm Pty. Ltd.*, arguing that "it remains necessary to identify some reason that would have led a

chemist to modify a known compound in a particular manner to establish prima facie obviousness of a new claimed compound" (Applicant Argument, Page 31). The reason is clear. Namely, the skilled artisan would have been motivated to make position isomers of the compounds taught by Merce-Vidal et al in view of In re Wilder. Specifically, in view of *In re Wilder*, a person of ordinary skill in the art at the time the invention was made would have found it prima facie obvious to make position isomers of the taught compounds in the reasonable expectation that the compounds would possess similar properties. Furthermore, in view of Filla et al, the skilled artisan would have found it obvious to make position isomers of Merce-Vidal et al wherein the substituent on the indole ring is moved from position 3 to position 1. The person of ordinary skill in the art would have found it prima facie obvious to do so in view of the fact that Filla et al teach compounds that also modulate 5-HT<sub>6</sub> and which support substitution at position 1 of the indole ring. Accordingly, the skilled artisan would have reasonably predicted that position isomers of Merce-Vidal et al, wherein the substituent is moved from position 3 to position 1, would possess similar properties to those compounds disclosed by Merce-Vidal et al

- 24. Claims 18 and 46 and drawn to medicaments including the compound of claim 1 or claim 9, respectively, an optionally at least one or more pharmacologically acceptable excipients. *Merce-Vidal et al* specifically teach "pharmaceutical compositions that comprise... an acceptable pharmaceutical excipient" (Page 11, Lines 6-8).
- 25. Claims 19 and 47 are drawn to the medicaments of claims 18 and 46, respectively, for the treatment of various conditions including, for example, disorders of

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the central nervous system. Merce-Vidal et al specifically teach "a medicament... useful for preventing or treating various disorders of the Central Nervous System" (Page 11, Lines 11-12). Although Merce-Vidal et al do not specifically teach that the disclosed medicaments are useful for treating, for example, Alzheimer's disease, as recited by instant claims 92 and 93, Applicant is advised that use limitations within product claims do not carry patentable weight unless the recitation of the intended use of the claimed invention results in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In the instant case, there is nothing to suggest that the prima facie obvious compounds taught by Merce-Vidal et al in view of In re Wilder and Filla et al, would not be capable of treating Alzheimer's disease. Indeed, Merce-Vidal et al specifically disclose that the taught compounds can be used to treat "cognitive memory disorders and senile dementia process, and other dementias in which predominates a cognition deficit" (Page 11, Lines 12-14). Thus, it is asserted that the prime facie compounds necessarily treat Alzheimer's Disease, absent evidence to the contrary. As stated in In re Best, Bolton, and Shaw, "Where... the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product" 195 USPQ 430, 433, 562 F2d 1252 (CCPA 1977). See also In re Fitzgerald 205 USPQ 594, 597, 619 F2d 67

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(CCPA 1980): the burden is shifted to the applicants to "prove that subject matter shown

to be in the prior art does not possess characteristic relied on."

26. Instant claims 74 and 84 are drawn to compounds according to claims 1 and 9,

respectively, wherein the compound is in the form of a physiologically acceptable salt

thereof. As disclosed by Merce-Vidal et al, the "present invention also relates to the

physiologically acceptable salts of the compounds" (Page 6, Lines 33-34).

27. Instant claims 75 and 85 are drawn to compounds according to claims 1 and 9,

respectively, wherein the compound is in the form of its enantiomers or

diastereoisomers or in the form of a mixture of at least two of its enantiomers and/or

diastereoisomers. Since Merce-Vidal et al do not specifically teach compounds in the

forms of enantiomers or diastereomers, it is understood and would have been obvious

to a person of ordinary skill in the art at the time the invention was made that the

compounds taught by Merce-Vidal et al are drawn to their racemic form. However, as

drafted, claims 75 and 85, which recite compounds in the form of a mixture of at least

two of its enantiomers, encompass the racemic compound, which is in the form of a

mixture of at least two of its enantiomers. Accordingly, claims 75 and 85 are also

rejected.

Claim Objections

28. Instant claims 83 and 91 are objected to for depending from a rejected claim.

**Double Patenting** 

29. The nonstatutory double patenting rejection is based on a judicially created

doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the

unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

30. Claims 1-14 and 18 and 46 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14, 18 and 46 of copending Application No. 10/566,101 in view of

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Laconde et al (J Enzyme Inhib Med Chem 18(2):89-94, 2003). Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons:

31. As discussed above, the instant application teaches the specie of Formula (Ia) N[1-(2-pyrrolidine-1-yl-ethyl)-1H-indole-5-yl]-naphthalene-1-sulfonamide (claim 8,
Example 17) having the following structure:

(Page 78, Example 17) which encompasses claims 1-8 and Formula (Ib) N-[1-(2-dimethylaminoethyl)-1H-indole-5-yl]-naphthalene-1-sulfonamide (claim 14, Example 3) having the following structure:

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(Page72, Example 3) which encompasses

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claims 9-14.

- 32. The '101 application teaches the compound species N-[1-(2-pyrrolidine-1-ylethyl)-1H-indole-6-yl]-naphthalene-1-sulfonamide (claim 8, Example 11) and N-[1-(2-dimethylaminoethyl)-1H-indole-6-yl]-naphthalene-1-sulfonamide (claim 14, Example 3). Accordingly, the only difference between the copending applications is the position of the sulfonamide on the indol ring; namely, position 5 (in the instant application) and position 6 in the '101 appliction.
- 33. MPEP 2144.09 states "Compounds which are position isomers (compounds having the same radicals in physically different positions on the same nucleus) or homologs (compounds differing regularly by the successive addition of the same chemical group, e.g., by -CH2- groups) are generally of sufficiently close structural similarity that there is a presumed expectation that such compounds possess similar properties. *In re Wilder*, 563 F.2d 457, 195 USPQ 426 (CCPA 1977).

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34. Furthermore, Laconde et al teach compounds having the sulfonamide on position

6 of the indol ring:

Reagents: i. MsCi, Et<sub>1</sub>N, CH<sub>2</sub>Ci<sub>2</sub>; ii. K<sub>2</sub>CO<sub>3</sub>, Acatone; iii. NH<sub>4</sub>Cl, Fe, propan-2-ol; iv. Pyridine, DMF

Compounds	N° of intermediates	Substitution on the indole ring	R	*(%) noitidial
7a	3a, 4a, 5a	5	H (6a)	. 0
76	3a, 4a, 5a	\$	2-COOMe (6b)	$13.64 \pm 0.7$
7e	3a, 4a, 5a	<b>\$</b>	4-SO <sub>2</sub> NH <sub>2</sub> (6c)	0
7d	3s, 4s, 5s	5	4-Mc (6d)	0
7e	3a, 4a, 5a	5	4-Cl (6e)	$17.25 \pm 0.8$
71	3a, 4a, 5a	5	4-OMc (6f)	$34.50 \pm 1.7$
7g	3a. 4a. 5a	5	4-CF <sub>7</sub> (6g)	0
7 <b>h</b>	3a, 4a, 5a	\$	2-CF <sub>3</sub> (6h)	9
71	3b, 4b, 5b	. 6	2-COOMe (6b)	15.90 ± 0.8
7	3c, 4c, 5c	7	2-COOMe (6b)	45.50 ± 2.2

(Page 93,

Figure 1). Accordingly, one of ordinary skill in the art would have been motivated to take sulfonamide group or similar variants, and place it at various positions on the indole ring, as they would be expected to have similar properties (for example at position 5, 6, or 7).

35. Claims 18 and 46 of the '101 application are drawn to medicaments containing an excipient. Accordingly, instant claims 18 and 46 are provisionally rejected.

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This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

- 36. Claims 1-14 and 18 and 46 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14, 18 and 46 of copending Application No. 10/566,403 in view of Laconde et al (J Enzyme Inhib Med Chem 18(2):89-94, 2003). Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons:
- 37. As discussed above, the instant application teaches the specie of Formula (Ia) N-[1-(2-pyrrolidine-1-yl-ethyl)-1H-indole-5-yl]-naphthalene-1-sulfonamide (claim 8, Example 17) which reads upon claims 1-8. Copending application teaches N-[1-(2-pyrrolidine-1-yl-ethyl)-1H-indole-7-yl]-naphthalene-1-sulfonamide (claim 8, Example 6).
- 38. As discussed above, the instant application teaches the specie of Formula (Ib) N-[1-(2-dimethylaminoethyl)-1H-indole-5-yl]-naphthalene-1-sulfonamide (claim 14, Example 3). Copending application teaches N-[1-(2-dimethylaminoethyl)-1H-indole-5-yl]-naphthalene-1-sulfonamide (claim 14, Example 1).
- 39. Claims 18 and 46 of copending application '403 are drawn to compositions comprising the compound and one or more pharmacologically acceptable excipients.
- 40. For the reasons discussed above claims 1-14 and 18 and 46 are provisionally rejected.

### Conclusion

The new ground(s) of rejection presented in this Office action were necessitated by Applicant's amendments to the claims. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CRAIG RICCI whose telephone number is (571) 270-5864. The examiner can normally be reached on Monday through Thursday, and every other Friday, 7:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information

system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/CRAIG RICCI/ Examiner, Art Unit 1614

/Ardin Marschel/ Supervisory Patent Examiner, Art Unit 1614